

March 11, 2020



Checkpoint Therapeutics Reports Full-Year 2019 Financial Results and Recent Corporate Highlights

NEW YORK, March 11, 2020 (GLOBE NEWSWIRE) -- Checkpoint Therapeutics, Inc. (“Checkpoint”) (NASDAQ: CKPT), a clinical-stage, immuno-oncology biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers, today announced financial results and recent corporate highlights for the full-year ended December 31, 2019.

James F. Oliviero, President and Chief Executive Officer of Checkpoint, said, “Checkpoint achieved significant progress in 2019. Notably, we continued to advance the development of our lead antibody product candidate, cosibelimab, which is in an ongoing, multicenter, registration-enabling Phase 1 clinical trial intended to support a potential Biologics License Application (“BLA”) submission for the initial indication of metastatic cutaneous squamous cell carcinoma (“CSCC”). Importantly, earlier this year, we announced confirmation by the FDA of the registration submission pathway in CSCC based on the ongoing clinical trial, which we are pleased to report is now over one-third enrolled. We also successfully closed on gross proceeds of approximately \$20 million in a November financing to extend our cash runway to support these efforts.” Mr. Oliviero continued, “We believe cosibelimab, upon approval, has the potential to be a market disrupting product through both its differentiated two-fold mechanism of action and our plan to enter the market at a price point substantially lower than the class of PD-1 and PD-L1 agents available today that generate over \$25 billion in annual sales.”

2019 and Recent Corporate Highlights:

- In March 2019, Checkpoint announced two new patent issuances by the U.S. Patent and Trademark Office and the European Patent Office for CK-101, our third-generation epidermal growth factor receptor (“EGFR”) inhibitor in Phase 1 development as a treatment for patients with EGFR mutation-positive non-small cell lung cancer (“NSCLC”). The patents cover CK-101 in the U.S. and Europe through at least August 2034, not including any potential patent term extensions.
- In June 2019, Checkpoint was added to the Russell 2000® Index.
- In September 2019, positive interim results for cosibelimab were presented at the European Society for Medical Oncology (“ESMO”) Congress 2019 in Barcelona, Spain. The poster presentation provided updated interim efficacy and safety results from the ongoing multicenter Phase 1 clinical trial of cosibelimab, including expansion cohorts in CSCC and NSCLC. A 50% objective response rate was observed in CSCC and a 40% objective response rate was observed in NSCLC. Cosibelimab appeared to be safe and well-tolerated with a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies.

- In November 2019, pharmacokinetic and target occupancy modeling data for cosibelimab were presented at the Society for Immunotherapy of Cancer 34th Annual Meeting. The poster, titled “Semi-mechanistic PK and target-occupancy modeling to support dose justification for anti-PD-L1 clinical candidate CK-301 (TG-1501) in oncology patients,” compared pharmacokinetic and tumor target occupancy data at steady state under various dosing regimens of cosibelimab to those of three marketed anti-PD-L1 monoclonal antibodies: atezolizumab, durvalumab and avelumab. The results demonstrated that cosibelimab dosed at 800 mg and 1,200 mg once every two weeks or every three weeks is expected to achieve over 99% PD-L1 target occupancy throughout the dosing interval, which is comparable to atezolizumab and durvalumab and higher than avelumab at approved doses.
- Also in November 2019, Checkpoint closed on gross proceeds of approximately \$19.6 million in an underwritten public offering of its common stock before deducting underwriting discounts and commissions and other offering-related expenses.
- In January 2020, Checkpoint announced confirmation of the registration path for cosibelimab in metastatic CSCC. U.S. Food and Drug Administration feedback supports the plan to submit a BLA based on data from the ongoing Phase 1 trial. Approximately one-third of enrollment is complete as of year-end in the cohort of patients with metastatic CSCC.

Financial Results:

- **Cash Position:** As of December 31, 2019, Checkpoint’s cash and cash equivalents totaled \$26.1 million, compared to \$22.0 million at December 31, 2018, an increase of \$4.1 million.
- **R&D Expenses:** Research and development expenses for the year ended December 31, 2019, were \$19.3 million, compared to \$33.7 million for the year ended December 31, 2018, a decrease of \$14.4 million. Research and development expenses for the year ended December 31, 2019, included \$3.2 million of non-cash stock expenses, compared to \$1.8 million in stock compensation expense for the year ended December 31, 2018.
- **G&A Expenses:** General and administrative expenses for the year ended December 31, 2019, were \$7.2 million, compared to \$6.6 million for the year ended December 31, 2018, an increase of \$0.6 million. General and administrative expenses for the year ended December 31, 2019, included \$3.2 million of non-cash stock expenses, compared to \$2.7 million in stock compensation expense for the year ended December 31, 2018.
- **Net Loss:** Net loss attributable to common stockholders for the year ended December 31, 2019, was \$24.7 million, or \$0.70 per share, compared to a net loss of \$36.4 million, or \$1.27 per share, for the year ended December 31, 2018.

About Checkpoint Therapeutics

Checkpoint Therapeutics, Inc. (“Checkpoint”) is a clinical-stage immunotherapy and targeted oncology company focused on the acquisition, development and commercialization of novel treatments for patients with solid tumor cancers. Checkpoint is evaluating its lead antibody product candidate, cosibelimab, a potentially differentiated anti-PD-L1 antibody licensed from the Dana-Farber Cancer Institute, in an ongoing Phase 1 clinical trial in checkpoint therapy-naïve patients with selected recurrent or metastatic cancers, including a registration-enabling cohort in cutaneous squamous cell carcinoma intended to support an initial Biologics License

Application submission. In addition, Checkpoint is evaluating its lead small-molecule, targeted anti-cancer agent, CK-101, a third-generation EGFR inhibitor, in a Phase 1 clinical trial for the treatment of patients with EGFR mutation-positive non-small cell lung cancer. Checkpoint is headquartered in New York City and was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.checkpointtx.com.

Forward-Looking Statements

This press release may contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our plans to submit one or more BLAs and seek approvals for cosibelimab, statements regarding the potential differentiation of cosibelimab, including a potentially favorable safety profile as compared to the currently available anti-PD-1 therapies, statements relating to the half-life and functional Fc domain of cosibelimab translating into potential enhanced efficacy, statements relating to how long we believe our cash will fund our operations, any statements relating to our growth strategy and product development programs, and any other statements that are not historical facts. Forward-looking statements are based on management’s current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks that regulatory authorities will not accept an application for approval of cosibelimab based on data from the ongoing Phase 1 study; risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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CHECKPOINT THERAPEUTICS, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2019	2018
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 26,077	\$ 21,995
Prepaid expenses and other assets	863	1,372
Other receivables - related party	26	1,532
Total current assets	26,966	24,899
Total Assets	\$ 26,966	\$ 24,899
 LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 7,257	\$ 12,317
Accounts payable and accrued expenses - related party	862	776
Total current liabilities	8,119	13,093
Total Liabilities	8,119	13,093
 Commitments and Contingencies		
 Stockholders' Equity		
Common Stock (\$0.0001 par value), 60,000,000 shares authorized		
Class A common shares, 7,000,000 shares issued and outstanding as of December 31,		
2019 and December 31, 2018	1	1
Common shares, 47,004,764 and 27,076,154 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively		
	5	3
Common stock issuable, 1,459,305 and 960,428 shares as of December 31, 2019 and December 31, 2018, respectively		
	2,510	1,748
Additional paid-in capital	136,442	105,451
Accumulated deficit	(120,111)	(95,397)
Total Stockholders' Equity	18,847	11,806
Total Liabilities and Stockholders' Equity	\$ 26,966	\$ 24,899

CHECKPOINT THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	For the year ended December 31,	
	2019	2018
Revenue - related party	\$ 1,708	\$ 3,506
Operating expenses:		
Research and development	19,325	33,654
General and administrative	7,233	6,592
Total operating expenses	<u>26,558</u>	<u>40,246</u>
Loss from operations	<u>(24,850)</u>	<u>(36,740)</u>
Other income		
Interest income	136	148
Other income	-	225
Total other income	<u>136</u>	<u>373</u>
Net Loss	<u>\$ (24,714)</u>	<u>\$ (36,367)</u>
Loss per Share:		
Basic and diluted net loss per common share outstanding	<u>\$ (0.70)</u>	<u>\$ (1.27)</u>
Basic and diluted weighted average number of common shares outstanding	<u>35,303,955</u>	<u>28,553,711</u>



Source: Checkpoint Therapeutics, Inc